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V.

AFFYMETRIX, INC.,

MULTILYTE LTD., a British corporation,

Defendant and Counterclaimant.

IN THE UNITED STATES	DISTRICT COURT
FOR THE NORTHERN DISTR	ICT OF CALIFORNIA
X, INC., a Delaware corporation,	No. C 03-03779 WHA
Plaintiff and Counterdefendant,	ODDED CD ANTING

SUMMARY JUDGMENT OF

NON-INFRINGEMENT

INTRODUCTION

In this patent case, plaintiff Affymetrix brings two motions for summary judgment of non-infringement based on (1) the term "binding agent" and (2) the phrases "determining the ambient concentrations" and "loading a plurality of different binding agents . . . onto a support means." Summary judgment with respect to the term "binding agent" is GRANTED. Multilyte does not oppose the motion based on the "loading" phrase, but reserves its right to appeal the Court's claim construction. The motion for summary judgment on that basis is also **GRANTED**. This order declines to rule on the remaining phrase "determining the ambient concentrations."

STATEMENT

Defendant Multilyte Ltd. is the assignee of the three patents-in-suit: United States Patent Nos. 5,599,720 ("the '720 patent"), 5,432,099 ("the '099 patent") and 5,807,755, ("the '755 patent'). The technology described therein relates to assays used by life-sciences researchers to detect the concentration of analytes, (i.e., hormones, proteins or other

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substances), in biological liquids such as saliva, serum, blood and urine. The parties have stipulated that "analyte" means "the substance to be measured and/or detected."

The '099 patent and the '755 patent (a continuation-in-part thereof) focused on methods of determining the concentrations of a plurality of analytes using a single assay. The '720 patent, however, was directed at the underlying method of determining the concentration of a single analyte using a small amount of binding agent. Reexamination proceedings for all three patents is currently ongoing. For this reason, this action was stayed in part on December 12, 2003. Subsequently, the stay was extended with respect to all proceedings on May 27, 2004. At a status conference held on December 2, 2004, the parties revealed that multiple reexaminations for each patent had been requested. But, some claims were found allowable in the First Office Action, dated July 8, 2004 (See Kappos Exh. 25).

To avoid prolonging the stay indefinitely, the Court decided to cautiously proceed with claim construction, at least with respect to four phrases that would likely appear in any claims ultimately allowed after all the reexamination proceedings were completed. Yet another reexamination request was granted on February 4, 2005 (ibid.). On February 22, 2005, a claim-construction order was issued. Following another status conference, at which the parties jointly agreed to proceed with summary-judgment motions, a second case-management order was issued on March 3, 2005, lifting the stay and granting the parties leave to file three motions to be heard simultaneously. Having come this far, with neither party now requesting a new stay, the Court will rule upon the pending motions. The two summary-judgment motions filed by Affymetrix are addressed here. Multilyte's motion for further claim construction of "binding agent" is discussed in a separate order.

Affymetrix, Inc. manufactures and sells DNA microarray systems under the trade name GeneChip[®]. It filed this declaratory judgment action, alleging non-infringement, invalidity and unenforceability of defendant's patents. Multilyte has asserted counterclaims of infringement. The GeneChip® microarray systems utilize oligonucleotide probes to detect the presence of complementary target strands via hybridization. While the accused products can be used for

either RNA analysis or DNA analysis, in both cases, only interactions between nucleic acids are involved (Fodor Decl. ¶¶ 50, 60).

To briefly summarize the method of manufacturing the GeneChip® microarray systems, oligonucleotide probes are synthesized upon a glass substrate support, using a series of photolithographic de-protecting and chemical coupling cycles (*id.* ¶¶ 27–39). Each nucleotide base is added one at a time, eventually building oligonucleotide strands of the intended length of 25 bases after 75 steps (*id.* ¶¶ 37, 39). This process is not completed with 100% efficiency, but a capping agent is used to truncate any oligonucleotides that fail to add the appropriate nucleotide base after each step (*id.* ¶ 35). The resulting microarray contains a heterogeneous population of oligonucleotides (*id.* ¶ 40).

There are over 1000 GeneChip® microarray systems featuring different oligonucleotide probes; these are customized to target different gene transcripts (id. ¶¶ 26, 42–48). Since this technology was first developed, improvements in photolithography has enabled Affymetrix to place over 1.3 million oligonucleotide probes on a single GeneChip® microarray (id. ¶ 20).

ANALYSIS

1. LEGAL STANDARD FOR SUMMARY JUDGMENT.

Summary judgment is proper where the pleadings, discovery and affidavits "show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FRCP 56(c). "One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24 (1986).

"Summary judgment is as appropriate in a patent case as in any other." *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984). Although the determination of patent infringement is usually a fact-intensive issue, "comparison of a properly interpreted claim with a stipulated or uncontested description of an accused device or process would reflect such an absence of material fact issue as to warrant summary judgment of infringement or noninfringement." *D.M.I. Inc. v. Deere & Co.*, 755 F.2d 1570, 1573 (Fed. Cir. 1985).

2. AFFYMETRIX PRODUCTS DO NOT USE A "BINDING AGENT"

The accompanying order granting Multilyte's motion for further claim construction of "binding agent" defines that term to mean "a molecule conventionally having one or at most two binding sites and an affinity constant (measured at equilibrium) of 10¹³ liters/mole or less." As explained therein, this definition expressly *includes* antibodies, binding proteins, receptor fragments and other proteins or fragments thereof, but *excludes* DNA, RNA, oligonucleotides or any other molecules comprised solely of nucleic acids.

There is no dispute that the GeneChip® microarray systems use oligonucleotide strands that are attached to a solid support and bind to complementary nucleic acids. By repeatedly urging the Court to adopt a construction of "binding agent" that expressly encompasses nucleic acids, Multilyte has effectively conceded throughout this litigation that there is no *protein* acting as a "binding agent" in the accused products. Indeed, its opposition brief essentially argued that there were genuine issues of fact for trial *if* the term "binding agent" was re-construed to encompass nucleic acids. Thus, the motion for summary judgment of non-infringement based on the term "binding agent" is **GRANTED**.

3. AFFYMETRIX PRODUCTS DO NOT "LOAD A PLURALITY OF DIFFERENT BINDING AGENTS... ONTO A SUPPORT MEANS"

The claim-construction order, dated February 22, 2005, held that "loading a plurality of different binding agents . . . onto a support means" meant "immobilizing two or more different binding agents on a solid support, with each location having a single binding agent." While the binding agent must be intact when it is loaded onto the solid support, the method of loading is not limited to those that were known or conventionally-used at the time of the invention. The Court reasoned that, even assuming *arguendo* that molecules comprised of nucleic acids were "binding agents," the invention would not cover methods that load individual nucleotides one by one onto the same location to create an oligonucleotide, (*i.e.*, growing an oligonucleotide from scratch), as opposed to loading the completed oligonucleotide in a single step.

Multilyte concedes that Affymetrix does not infringe any patent claims containing the phrase "loading a plurality of different binding agents . . . onto a support means" as it has been

For the Northern District of California

construed (Opp. 1, fn.1). It does not oppose the motion for summary judgment.	Accordingly,
summary judgment on this basis is GRANTED .	

CONCLUSION

For the reasons stated above, the motion for summary judgment of non-infringement with respect to the term "binding agent" is **GRANTED**. The unopposed motion for summary judgment on the basis of the phrase "loading a plurality of different binding agents . . . onto a support means" is also GRANTED. In light of these rulings, this order declines to reach the issue of whether Affymetrix is also entitled to summary judgment of non-infringement based the phrase "determining the ambient concentrations." Judgment will be entered accordingly.

IT IS SO ORDERED.

Dated: April 28, 2005	/S/ WILLIAM ALSUP
	WILLIAM ALSUP
	UNITED STATES DISTRICT JUDGE